SUMMARY OF EXPERIENCE WITH THE DALKON SHIELD TO DATE

March 15, 1972

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SUMMARY OF EXPERIENCE WITH THE DALKON SHIELD TO DATE

The following is a tabulation of the experience with the Dalkon Shield as published or reported at meetings by a number of investigators.

The results presented below reflect the performance of the Dalkon Shield at each of the facilities where it was used. Discrimination of a number of factors which might influence the outcome of such studies is not made except for the indicators of parity and age. Reprints of the published articles from which some of this information is excerpted are attached. Life Table methods have been used in most of the calculations of these results.

I. Davis, Hugh J., M.D. The shield intrauterine device. American Journal of Obstetrics and Gynecology. 106(3)455-6 (February 1) 1970.

NOTE: This study was carried out at the Family Planning Clinic of the Johns Hopkins Medical School, Department of Obstetrics and Gynecology, Baltimore, Maryland, USA. The presented rates are at one year:

Type of Termination

First insertions	640 (3549 woman months of use)
Pregnancy rate	1.1
Expulsion rate	2.3
Medical removals	2.0
Personal removals	0.6
Continuation	94.0

II. Since the above, Dr. Davis has updated the results in a paper presented at the Family Planning Research Conference, University of Exeter, England, (September 27-28, 1971) with the title, "Performance of loop and Shield Intrauterine Contraceptive Devices". Results:

FIRST YEAR NET RATES PER 100 FIRST INSERTIONS
COMPARING LOOP AND SHIELD INTRAUTERINE DEVICES

	LOOP	SHIELD
Pregnancy rate	2.9	1.5
Expulsion rate	14.5	2.2
Medical removals	8.3	2.6

SECOND YEAR NET RATES PER 100 FIRST INSERTIONS
COMPARING LOOP AND SHIELD INTRAUTERINE DEVICES

	LOOP	SHIELD
Pregnancy rate	1.3	1.0
Expulsion rate	2.5	0.0
Medical removals	10.9	2.6

III. Ostergard, Donald R., M.D.; Broen, E. M., M.D. The Dalkon Shield: A Clinical Evaluation. Contraception. 4(4)313-7 (November) 1971.

NOTE: This study was carried out at Pap and Family Planning Clinic of Harbor General Hospital, Torrance, California by the Department of Obstetrics and Gynecology, UCLA School of Medicine. The results presented are at 9 months, and it should be noted that the incidence of events represented is on the total population, i.e. multiparous and nulliparous subjects.

Type of Termination

First insertions - nulliparous patients	327 (1222 woman months of use)
First insertions - multiparous patients	915 (4193 woman months of use)
Pregnancy rate	1.1*
Expulsion rate	1.0*
Removal**	9.7*
Continuation	88.2*

* Combined multiparous and nulliparous patients
**Bleeding, pain or other medical reasons

IV. Earl, Thad J., M.D. The Shield Intrauterine Device. Family Practice 4(3) (September) 1971.

NOTE: These results represent the experience of the investigator in his own private practice, indicating the possibility of population characteristics different than those of a clinic population.

Type of Termination

First insertions	536 (4633 woman months of use)
Pregnancy rate	0.5
Expulsion rate	0.2
Medical removals	2.7
Personal removals	0.2
Continuation	94.5

V. Melton, Robert J., M.D.; Shelton, James, M.D. Pill versus IUD: Continuation Rates of Oral Contraceptive and Dalkon Shield Users in Maryland Clinics. Contraception. 4(5)319-26 (November) 197..

NOTE: It should be noted that this is a retrospective study whose purpose was to evaluate overall continuation rates and not incidence of events. Thus, incidence of specific events may have been biased by the sampling techniques.

(See tables on next page)

CONTRACEPTIVE USE STATUS AT COMPLETION OF STUDY
DALKON SHIELD - PILL COMPARISON STUDY
MARYLAND COUNTIES - JULY 1970

Contraceptive Use Status	Shield Users		Pill Users	
	No.	%	No.	%
Accidental Pregnancy	4	2.2	14	7.7
Expulsion	7	3.8	-	-*
Discontinued, medical reason	15	8.3	13	7.2
Discontinued, personal reason	5	2.8	38	21.0
Discontinued, pregnancy desired	4	2.2	3	1.7
Release from Follow-up	5	2.8	20	11.0
Lost to Follow-up	14	7.7	15	8.3
Continuing Use	127	70.2	78	43.1
Total	181	100.0	181	100.0

*Category not applicable.

NET CONTINUATION RATES BY METHOD AND MONTHS OF USE
DALKON SHIELD - PILL COMPARISON STUDY
MARYLAND COUNTIES - JULY 1970

Months of Use	Shield Users		Pill Users	
	Rate	95% Confidence Limits	Rate	95% Confidence Limits
3	93.2	95.1 - 91.3	90.6	92.9 - 88.3
6	87.0	89.8 - 84.2	79.4	82.7 - 76.1
9	80.1	83.7 - 76.5	69.1	73.0 - 65.2
12	69.9	74.7 - 65.1	55.4	60.0 - 50.8

VI Gabrielson, Mary O., M.D.; Goldsmith, Sadja, M.D.; Strangeland, Susan, M.S.W. Use of the Dalkon Shield in Young Nulliparas: A Preliminary Report, Presented at the Ninth Annual Meeting of the American Association of Planned Parenthood. Kansas City, Missouri (April 5-6) 1971.

NOTE: This study has been carried out at the Oakland and San Francisco Planned Parenthood centers in California. The authors use no pre-insertion analgesic. Thirty percent of the subjects were under the age of twenty and 51% were 20-24 years of age. The rates reported are at nine months.

Type of Termination

First insertions	756 (3653 woman months of use)
Pregnancy rate	1.9
Expulsion rate	1.2
Medical removal	14.9
Personal removal	1.8
Continuation	80.2

VII. Dodds, G., M.D. Results reported at the Family Planning Research Conference, University of Exeter, England (September 27-28) 1971.

NOTE: This study was carried out at the Family Planning Association of Hong Kong. The statistics were calculated by the Pathfinder Fund International IUD Program. The rates presented are at ten months.

Type of Termination

First insertions	(3324 woman months of use)
Pregnancy rate	2.1
Expulsion rate (first)	0.8
Expulsion rate (later)	0.0
Removals (bleeding and pain)	6.4
Removals (other medical)	2.2
Removals (personal)	1.8
Pregnancy desired	0.7
Continuation	86.0

VIII. Crist, Takey, M.D. The Dalkon Shield in the Nulliparous Patient, presented at the District IV meeting of the ACOG in Norfolk, Virginia (October 25-26) 1971.

NOTE: This study was carried out at the Family Planning Clinic of the University of North Carolina, Department of Obstetrics and Gynecology. The rates reported are at twelve months. The majority of the subjects were students at the University of North Carolina.

Type of Termination

First insertions	138 (1222 woman months of use)
Pregnancy rate	1.4
Expulsion rate	1.4
Medical removals	7.4
Personal removals	5.1
Pregnancy desired	1.4
Continuation	83.3

COMMENT

The above statistics are cited without the benefit of extensive commentary regarding study conditions or appropriate comparisons. Review of the attached reprints should provide a more critical perspective. In the case of the studies which have not been published yet, reprints will be added to this report as soon as they are available.

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The shield intrauterine device

A superior modern contraceptive

HUGH J. DAVIS, M.D.
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Improvements in the performance of sophisticated intrauterine devices are producing results greatly superior to the empirically designed devices used in clinical practice Pregnancy rates have been reduced with these modern devices to levels superior to the sequential oral contraceptives and only slightly inferior to the protection afforded by combined oral contraception. Expulsion and removals for bleeding complications have been greatly reduced with the modern shield type of IUD, yielding continuation rates distinctly superior to barrier methods, oral contraceptives or the older types of intrauterine device in general use

FOR THE past 7 years, trials of intrauterine devices in more than 5,000 women have been under way at our institution Constant improvements have been noted, leading to the development of modern devices of superior performance Recent experience with a shield design approaches the ideal of combining very low pregnancy rates with minimal side effects These modern devices are demonstrating such excellence as to justify a revision of current attitudes toward the efficacy of intrauterine devices

Several features distinguish the Dalkon Shield device* as compared with the old ring, bow, loop, and spiral type of IUD The shield contour (Fig. 1) conforms to the midrange of uterine cavity, as determined by silicone casts prepared from normal uteri.[1] The device is light and flexible to minimize cramping. Small lateral fins promote retention and permit accommodation to uterine contractions and variations in uterine shape. A central membrane increases endometrial surface contact, as well as precluding bowel strangulation in the event of perforation, a rare complication observed with closed loop design IUD's.[2] Relative to the generally available plastic IUD's, the shield is less bulky, simple to insert and exceptionally well tolerated

The first year of experience with the Dalkon shield at Johns Hopkins totals 610 primary insertions, the majority fitted 6 to 12 weeks post partum. The series includes 558 clinic and 82 private patients. There have been 5 pregnancies, 10 expulsions, 9 removals for medical reasons, and 3 removals for personal reasons There were 51 nulliparous patients in the series, with one pregnancy, two removals, and 0 expulsions Among the 82 private patients in the series, we have experienced 1 pregnancy, 2 removals, and 0 expulsions.

From the Department of Obstetrics and Gynecology, Johns Hopkins University School of Medicine

Support of the Clayton Baker Trust is gratefully acknowledged.

**Dalkon Shield, 341 Shore Road, Greenwich, Connecticut 06830.*

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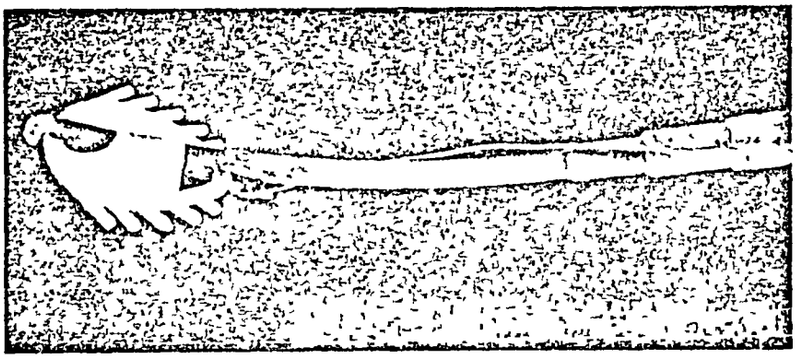

Fig. 1. Oblique view of shield intrauterine device on preloaded inserter Centimeter graduations on the disposable inserter promote accurate fundal fittings

Table I. Experience with shield device at Johns Hopkins for 1968-69 (rates at one year, life table method)

	No	*%*
First insertions	640	100.0
Pregnancy rate		1.1
Expulsion rate		2.3
Medical removals		2 0
Personal removals		0.6
Continuation rate		94 0

Data analysis at the end of the first year (Table I) covers 3549 woman-months of experience Calculated events by the life table method[4] are 1 1 pregnancies, 2 3 expulsions, 2.0 medical removals, and 0 6 personal removals per 100 woman-years The net retention rate at one year is 94 0 per cent ± 1.2 per cent for one standard error This level of continuation is quite superior to the empirically designed devices in common use

In our experience, both the protection against pregnancy (99 per cent) and the tolerance (96 per cent) achieved by this modern shield type of IUD is superior to sequential oral contraceptives Comparison of failure rates may be made with the generally available types of oral and intrauterine devices as reported in 1969 by the Food and Drug Administration Advisory Committee on Obstetrics and Gynecology[3] Pregnancy rates listed for the combined orals are 0 7 per cent, for the sequentials 1 4 per cent, for the loop 2 7 per cent and for the double coil 2 8 per cent Only the combined type of oral contraceptive offers a slightly greater protection (0 4 per cent) than our results with the shield intrauterine device.

The high retention rates and low pregnancy rates experienced with the shield device in both nulliparous and multiparous patients indicate good compatibility with normal uterine physiology Effective protection against pregnancy is achieved with a modern IUD without the actual and potential hazards of systemic medication for birth control Taken altogether, the superior performance of the shield intrauterine device makes this technic a first choice method of conception control

REFERENCES

1. Davis, H J, and Israel, R Proceedings Second International Congress on Intrauterine Contraception, Oct 2-3, 1964, New York, Amsterdam, 1964, Excerpta Medica Foundation International Congress Series No 86, pp 135-141.
2. FDA Report on Intrauterine Contraceptive Devices, January, 1968.
3. FDA Report on Oral Contraceptives, September, 1969.
4. Tietze, C Intrauterine Contraception Recommended Procedures for Data Analysis—Studies in Family Planning, Suppl 18, April, 1967.

PERFORMANCE OF LOOP AND SHIELD INTRAUTERINE CONTRACEPTIVE DEVICES

Hugh J. Davis, M.D.

During the past decade, intrauterine contraception has achieved increasingly widespread acceptance because the method offers a unique combination of medical safety, efficacy, permanence and reversibility as compared with other methods of conception control. Nevertheless, even broader use of IUD's has been inhibited by terminations due principally to expulsions and medical removals. Design factors such as size, shape, flexibility, surface area and composition of material undoubtedly influence clinical efficacy, hence comparisons of IUD performance can point the way towards improved results with this birth control method. The present study is a comparison of the loop and shield types of IUD, relating design differences to the incidence of expulsions, pregnancies and removals for medical reasons.

MATERIALS AND METHODS

The patient material consists of 759 women fitted with the D loop and 626 women fitted with the standard size shield device at the Johns Hopkins Hospital and the Maryland Planned Parenthood Association. Insertions were usually carried out 10 weeks or more postpartum during menstrual flow or withdrawal bleeding induced by the prior administration of oral contraceptives. No immediate, early postpartum or post-abortal insertions are included in this study. The generally recognized relative and absolute contraindications to the use of intrauterine devices were observed (1).

At the time of insertion, the cervix was cleansed with an antiseptic solution of iodine (Wescodyne® or Betadine®). Sterile

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devices were used and instruments were sterilized by autoclaving or by immersion in iodine antiseptic solution for a minimum of five minutes. A single tooth tenaculum was routinely employed to straighten the axis of the cervico-uterine juncture. Routine exploration of the uterine cavity with the sound prior to insertion was practiced. In this series, the choice of device, whether loop or shield, was determined by the day on which the patient appeared for insertion.

Routine follow-up examinations were scheduled at two month post-insertion and at six monthly intervals thereafter. Insertions and removals were carried out by gynecologists experienced in the use of intrauterine devices and by residents in training, while patient interviewing and routine follow-up was generally performed by nurse practitioners. The two types of device are shown in fig. 1. The D loop was chosen as a standard of comparison because it has achieved the broadest utilization among the various linear design intrauterine devices introduced in the early 1960's, while the shield design represents a second generation type of device designed for improved retention and better uterine compatibility.

RESULTS

The net rates for pregnancies, expulsions and medical removals per 100 first insertions were computed by life-table methods. The results for the first year of IUD use are presented in Table 1.

FIRST YEAR NET RATES PER 100 FIRST INSERTIONS
COMPARING LOOP AND SHIELD INTRAUTERINE DEVICES

	LOOP	SHIELD
Pregnancy Rate	2.9	1.5
Expulsion Rate	14.5	2.2
Medical Removals	8.3.	2.6

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Spontaneous expulsion was the predominant cause of device loss for the loop, accounting for about 60 percent of the total terminations in the first 12 months of use. Expulsions occurred nearly seven times as frequently with the loop (14.5 percent) as among patients fitted with the shield (2.2 percent).

Medical removals, principally for pain and/or bleeding complications accounted for one third of the terminations among loop wearers in the first year of use, being observed three times as frequently (8.3 percent) among loop wearers as among shield wearers (2.6 percent). Twice as many pregnancies occurred among the loop wearers (2.9 percent) as compared with shield wearers (1.5 percent).

The net rates for pregnancies, expulsions and medical removals in the second year of use are presented in Table 2:

SECOND YEAR NET RATES PER 100 FIRST INSERTIONS
COMPARING LOOP AND SHIELD INTRAUTERINE DEVICES

	LOOP	SHIELD
Pregnancy Rate	1.3	1.0
Expulsion Rate	2.5	0.0
Medical Removals	10.9	2.6

Medical removals replaced expulsions as the major cause of patient loss during the second year of IUD use, resulting in terminations by an additional 10.9 percent of loop wearers and 2.6 percent of women fitted with the shield device. Both pregnancies and expulsions occurred infrequently in the second year of use, accounting for termination by 3.8 percent of loop wearers and 1.0 percent of shield wearers. At the end of 24 months of use, the continuation rate among women fitted with the loop device was 59.6 percent, while the continuation rate was 90.1 percent for the women wearing the shield intrauterine device.

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CONCLUSIONS

Substantial differences in performance can be demonstrated to exist in comparing the older linear design intrauterine devices developed in the early 1960's with the second generation devices now achieving increasing clinical utilization. The differences in performance which can be related to differences in design are manifest in both the first and second years of use in comparing the results with the loop and shield devices. With respect to all major causes of IUD termination - pregnancies, expulsions and medical removals - the shield device has demonstrated superior performance.

While factors of patient selection and management certainly can influence results with intrauterine contraception, the loop device in this study does not appear biased by such factors, since the results are similar to those reported by Tietze ( ) in the 9th progress report of the Cooperative Statistical Program. At the end of 24 months of use 20.9 percent of loop wearers had experienced expulsion in the CSP series, as compared with 17.0 percent expulsions in our patient material. In the category of medical removals, 19.2 percent terminated use of the loop for this reason in our series and 25.8 percent in the CSP series.

The shield device, which is designed to fit the contours of the average uterine cavity and highly accommodative to lateral compressive forces, was removed for medical reasons in 5.2 percent of our patients in the first two years of use, the relatively stiffer and bulkier loop design requiring removal four times as frequently in both the present study and the CSP program. Over-all, the clinical efficacy of the modern shield device is greatly superior to that of

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the loop, as reflected in continuation rates of 90.1 for the shield at the end of two years and 59.6 percent among loop wearers. Based on these differences in performance, the broader use of second generation intrauterine devices such as the shield can be expected to greatly improve both clinical and demographic results with this method of contraception.

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1. Davis, H.J.: INTRAUTERINE DEVICES FOR CONTRACEPTION - THE IUD. The Williams and Wilkins Company, Baltimore, 1971.

2. Tietze, C. and Lewit, S.: Evaluation of intrauterine devices: Ninth progress report of the Cooperative Statistical Program. Studies in Family Planning 55:1-40, 1970.

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K-8339

THE DALKON SHIELD: A CLINICAL EVALUATION*

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ABSTRACT

This prospective study was undertaken in order to provide a further evaluation of the effectiveness of the Dalkon Shield. In a series of 348 nulliparous and 978 multiparous patients, 10 pregnancies and 10 expulsions occurred. Shields were removed in 81 instances. The cumulative Life Table rates after 9 months for expulsion and pregnancy were 1.02% and 1.06%, respectively. The medical removal rate was 9.36%. No perforations occurred.

*Presented at the Ninth Annual Meeting of the American Association of Planned Parenthood Physicians, Kansas City, Missouri, April 5-6, 1971.

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INTRODUCTION

The contraceptive effectiveness of numerous intrauterine devices is the subject of intense clinical investigation. Varying degrees of efficacy have been reported for devices of various sizes and shapes. The surface area of endometrium in contact with the device has been stated to be one of the important parameters in determining its effectiveness (1). Of the IUD's currently available, the Shield covers the greatest surface area of endometrium. Preliminary clinical evaluation of this new device suggests that it is a superior intrauterine contraceptive (2). This prospective study was undertaken to provide a further evaluation of its effectiveness.

MATERIAL AND METHODS

Appropriate nulliparous or multiparous size Shields were inserted into 348 nulliparous and 978 multiparous patients who requested contraception by means of an intrauterine device. The standard insertion technique employed is as follows: cervical tenaculum to grasp the anterior lip, cleansing of ectocervix with benzalkonium chloride (1:750), paracervical block (nulliparous patient); uterine sounding to ascertain fundal depth, insertion of Shield to depth of previous sounding; and disengagement of the inserter.

Follow-up examinations were performed two months after insertion and then at intervals of six months.

Data on initial insertions in 327 nulliparous patients (1,222 women-months of use) and 915 multiparous patients (4,193 women-months of use) are available for study. Data are tabulated by the Life Table method (3).

RESULTS

Ten pregnancies occurred with the device in situ in these study patients. No pregnancies occurred following unnoticed expulsion. The time of pregnancies occurring with the Shield in situ is shown in Table I. The cumulative probability of non-pregnancy by the Life Table method is 98.94% after ten months.

Expulsions occurred in 10 patients. Expulsions were either noticed by the patient or the device was found in the vagina or external cervical os at the time of periodic examination. The time of expulsion is given in Table I. The cumulative probability of non-expulsion is 98.98% after ten months.

Shield were removed in 81 patients. The time of removal and the reasons for removal are given in Tables I and II. The cumulative probability of non-removal for medical reasons by the Life Table method after ten months is 90.64%. The probability for non-removal for all reasons is 88.92%.

TABLE I

Time of Occurrence and Number of Pregnancies, Expulsions and Removals

Months of Use	Number of Women	Pregnancy	Expulsion	Removal
< 2	34	6	8	46
3-6	439	4	2	26
7-10	769	0	0	9

TABLE II

Reasons for Removal

	Nulliparous	Multiparous
Bleeding	9	16
Cramping	12	4
Both	6	16
Desire Pregnancy	4	5
Personal	2	7

Menstrual flow was increased in 60 to 80% of patients by 2 to 4 days during the first two cycles with o decrease in flow during subsequent cycles. Few patients experienced o primary decrease in menstrual flow. The effect on menses is similar for both nulliparous and multiparous patients. Continued intermenstrual spotting occurred in up to 14% of patients, with only 6% experiencing this symptom beyond the second month.

No perforations have been noted to occur.

DISCUSSION

The acceptance of an intrauterine device as a means of spacing childbirth depends upon elimination of complications. The most important complications are pregnancies and bleeding and/or cramping. If an intrauterine device can be placed within the uterus with the assurance that the probability of expulsion is low and that the occurrence of pregnancy is infrequent, its significance as an effective contraceptive becomes apparent. The Shield has demonstrated low cumulative rates in both categories as calculated by the Life Table method. These rates have remained constant between five and ten months of use.

A comparison with other intrauterine devices by cumulative event rates as calculated by the Life Table method for 9 months of use in a different population group is given in Table III. [Data on the steel spring, loop D, Shell loop and double coil are courtesy of Dr. Christopher Tietze (4)]. The Dalkon Shield compares favorably with other devices with regards to pregnancies, expulsions, and removals.

TABLE III

Comparison of Intrauterine Devices
(Nine Month Cumulative Event Rates)

	Steel Spring*	Loop D*	Shell Loop*	Double Coil*	Shield
Pregnancy	1.2	1.8	1.0	2.1	1.1
Expulsion	5.1	8.4	2.7	14.5	1.0
Removal**	18.0	14.0	12.0	17.2	9.7
Continuation Rate	75.7	75.8	84.3	66.2	88.2

*From reference 4, Tietze.
**Bleeding, pain or other medical reasons.

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CONCLUSIONS

The Dalkon Shield has been found to have expulsion and pregnancy rates of 1.02% and 1.06%, respectively, with a medical removal rate of 9.36% at the end of nine months as calculated by the Life Table method. No perforations have occurred. Continued acceptability with prolonged usage is evident.

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4. Tietze, C.: Personal Communication.

END *

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The Shield Intrauterine Device

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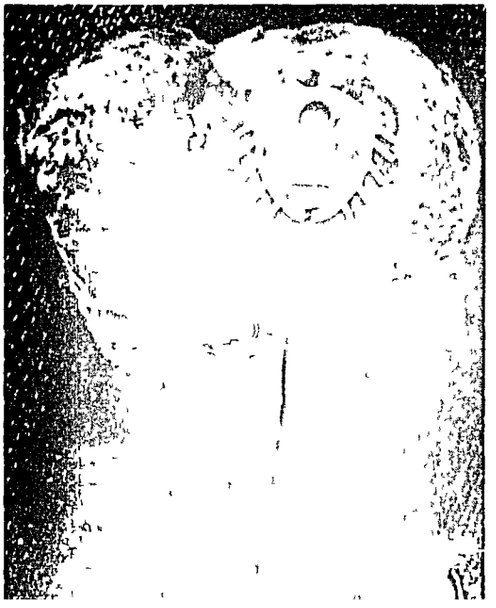
Recent advances in design, materials and insertion techniques have made the new generation of intrauterine devices (IUDs) effective methods of contraception. This article briefly describes clinical experience with a recently developed IUD, the Dalkon Shield® The shape of this device conforms anatomically to the size and shape of the average uterine cavity This was substantiated by transections of uteri from patients who had hysterectomies (*Figure 1*). Micrometer measurements of the uterine cavities correlated well with the measurements of the IUD.

Insertions were performed in 536 patients ranging from 17 to 51 years of age Total experience in this study covers 4,633 woman-months Two patients became pregnant (pregnancy rate 0 5 percent by the life-table method) One aborted after three and one-half months with the device in place and the other became pregnant as the result of a partial expulsion There were 12 removals· six for medical reasons (prolonged menses, intermenstrual spotting, cramping and pain), five for planned pregnancies and one for personal reasons. The medical removal rate was 2.7 percent and the personal removal rate was 0 2 percent One spontaneous expulsion occurred The expulsion rate was 0 2 percent and the continuation rate was 94.5 percent

Sterile technique was used in all cases Each patient was given 0 5 mg of atropine, intramuscularly, 20 minutes before insertion. This helped to reduce the bradycardia which is sometimes associated with IUD insertions —especially in nulliparous patients

FIGURE 1 Transected uterus with the Shield IUD in place.



Contraindications for insertion of the device included suspected pregnancy, acute or subacute salpingitis, suspected neoplasia, cervical stenosis, endometritis, uterine cavities less than 5 cm , dysfunctional uterine bleeding and myomas which distorted the uterine cavity.

Three patients developed endometritis from one to six months after insertion They were treated with antibiotics and responded satisfactorily It was not necessary to remove the device

Prolonged menstrual flow occurred during the first three to four cycles in approximately 50 percent of the patients Moderate cramping after insertion, lasting for several hours, was experienced by 30 percent of the patients, especially the nulliparas

The device was inserted during the menses for the following reasons (1) the patient was definitely not pregnant, (2) the cervical os was more patent at that time, and (3) the mechanics of insertion often cause spotting, which was not noted during menstruation. Patients were re-examined at six to eight weeks after insertion to check the string position at the cervical os Thereafter, they were checked at six-month intervals A continuing record of the string position helped detect early partial expulsions. Follow-up included a routine Pap smear and evaluation of a menstrual record kept by the patient

In the postpartum patient, insertion was done six to 12 weeks after delivery, when the uterus was completely involuted and firm. The patient was first placed on either a one- or two-month course of oral contraceptives, two to three weeks postpartum, as a precaution against early pregnancy The IUD was then inserted at the time of the second menstrual period.

Of the patients in this series, 394 were multiparous and 142 were nulliparous In the nulliparous patients, there were no pregnancies, no expulsions and only one removal The nulliparas' acceptance and tolerance of the Shield device was especially gratifying.

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K-0339

PILL VERSUS IUD: CONTINUATION RATES OF ORAL CONTRACEPTIVE AND DALKON SHIELD USERS IN MARYLAND CLINICS

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James D. Shelton, B.A.

From the Family Planning Evaluation Activity+, Epidemiology Program, Center for Disease Control, Atlanta, Georgia 30333, and the Maryland State Department of Health, Baltimore, Maryland 21201, with the cooperation of the Department of Population Dynamics, Johns Hopkins University School of Hygiene and Public Health, Baltimore, Maryland.

ABSTRACT

One hundred eighty-one oral contraceptive patients were matched to 181 Dalkon Shield patients by age, race, parity, and county in the family planning clinics of three Maryland counties. The continuation rate for Shield patients was 69.9 percent at 12 months as opposed to 55.4 percent for the pill patients. Fourteen of the pill patients became pregnant unintentionally as opposed to four of the Shield patients. Two hypotheses for the difference in continuation are offered. Patients wanting a temporary contraceptive method for purposes of child spacing may select orals, patients wanting a more permanent method to limit family size may select the IUD. Alternatively, the greater inconvenience of pills may be responsible for the lower continuation rate with that method.

INTRODUCTION

Family planning services have been available to low-income women in all Maryland counties since January 1967. The service is coordinated through the Maryland State Department of Health and Mental Hygiene, Division of Maternal and Child Health, and is administered through county health department facilities+. An automated data system was introduced in the clinics in July 1968,

*Funded in part through Center for Population Research, National Institute of Child Health and Human Development, National Institute of Health, Bethesda, Maryland.

+Clinics in Baltimore City are administered separately by the Baltimore City Health Department.

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and the system has operated continuously ever since, monitoring attendance in clinics (1).

Routine analysis of the data produced by the record system has indicated some variation in patient attendance according to the type of contraceptives used. Intrauterine device users have been found to be more apt to keep appointments than users of oral contraceptives. However, the data system provides no information on the proportions of patients continuing to use the various methods at points in time, and it does not indicate reasons for which patients discontinue use.

The present study was undertaken to determine the continuation rates of a matched sample of Dalkon Shield (IUD) and oral contraceptive users in Maryland family planning clinics.

METHOD

The study was carried out in three of Maryland's 23 counties a prosperous suburban county near Baltimore, a predominantly white county in rural Western Maryland, and a rural Eastern Shore county with a large black population. The counties represented a cross-section of the State's family planning program with regard to the percent of target population actively enrolled in the county clinics.

A list of all Shield and pill patients in the three counties was printed from computer records. Patients who entered the program before July 1, 1968, or after July 1, 1970, were eliminated to give the study a 24-month focus Patients for whom the given method was not the first method used in clinic were also eliminated, this ensured that no patients would be included in both Shield and pill groups.

A sample of Shield patients was then taken from the computer list using random number tables Again using random number tables, a pill patient was matched to each shield patient by county, age, race, and parity Pill patients were matched to Shield patients rather than vice-versa because there were many more pill patients in the counties. In almost all cases a match could be made. If not, patients from adjacent matching cells were used, with priority given to parity and race.

Charts were then reviewed in the county health departments to obtain as much information as possible on methods used, complications, pregnancies, and reasons for termination. If records were complete and a visit had been made after June 1, 1970, then no further information was sought. If records were incomplete, patients were contacted by telephone or home visit

There were 362 patients in the sample, with half on each method of contraception. Clinic records provided sufficient information on 52 percent, telephone calls on 26 percent, home visits on 12 percent, and 10 percent were lost to follow-up.

Data were then analyzed for periods of contraceptive use and type of termination. The period of use was defined as the number of ordinal months completed between the date of the initial clinic visit and the date of the most recent visit or the date at which

the patient was contacted in the study. Patients who had been lost to follow-up were given credit only to the date of their most recent visit; if they made only one initial visit and then did not return they were dropped at zero months of use. Short periods of non-contraception for pill patients were included, as there was no practical way to measure and exclude them Pill patients were not allowed months of use for pills dispensed at their most recent visit. Types of terminations were classified by Tietze's definitions (1). In cases with pregnancies, expulsions, and removals, the period of use was terminated at the estimated date of conception, or the date at which the expulsion or removal took place. Data were then analyzed by the life-table method at the computer facilities of the Johns Hopkins University School of Hygiene and Public Health, Department of Population Dynamics.

RESULTS

In Table I the distribution of study patients by age, race, and parity is compared with the distribution for all patients in the three counties. While the county family planning population is almost equally white and black, the study sample is weighted toward whites. Study patients are somewhat younger than the clinic population, and their parity is concentrated slightly more around parity one and two, but in general they conform quite closely to parity of others in the counties.

The distribution of patients by final status in the study is given in Table II There were 14 pregnancies among pill patients and only four among Shield patients. While 38 pill patients terminated for "personal reasons", only five Shield patients did so. Release from follow-up means the patient transferred to a private physician, was sterilized, or transferred to a clinic in another state. In all, 54 Shield patients and 103 pill patients were no longer continuing use by the cut-off date.

Continuation rates, calculated by the life-table method, are given in Figure 1 and Table III. The Shield patients have higher continuation rates at all points except the first two months. Continuation rates for Shield and pill patients, respectively, are 93.2 percent and 90.5 percent at three months, 87.0 percent and 79.4 percent at six months, 80.1 percent and 69.1 percent at nine months, and 69.9 percent and 55.4 percent at 12 months. Standard errors for the rates are shown in Figure 1. Total woman-months of use in the study are 1,361.5 for the Shield and 1,624.0 for the pill.

DISCUSSION

The continuation rates for Dalkon Shield and oral contraceptives were strikingly different--a finding reported by others who have analyzed other IUD's. Hall analyzed data from Baltimore City clinics and found 1-year continuation rates of 63 percent for IUD's and 53 percent for orals (2). Tietze, summarizing data on extended use effectiveness in Buffalo, Atlanta, and

TABLE I

TOTAL WOMEN IN COUNTY FAMILY PLANNING PROGRAMS AND
WOMEN IN SHIELD AND PILL STUDY GROUPS BY RACE, PARITY, AND AGE
SHIELD - PILL COMPARISON STUDY
MARYLAND COUNTIES - JULY 1970

	All Women		Shield Users		Pill Users	
	No.	%	No.	%	No.	%
Race						
White	1,786	*49.3*	114	*63.0*	113	*62.4*
Black and Other	1,836	*50.6*	67	*37.0*	68	*37.6*
Unknown	3	*0.1*	0	*0.0*	0	*0.0*
Total	3,625	*100.0*	181	*100.0*	181	*100.0*
Parity						
0	90	*2.5*	4	*2.2*	4	*2.2*
1	1,173	*32.4*	66	*36.4*	66	*36.4*
2	869	*23.9*	44	*24.3*	47	*26.0*
3	569	*15.7*	24	*13.3*	23	*12.7*
4-5	591	*16.3*	27	*14.9*	27	*14.9*
6 or more	333	*9.2*	16	*8.8*	14	*7.7*
Total	3,625	*100.0*	181	*100.0*	181	*100.0*
Age						
<20	780	*21.5*	51	*28.2*	46	*25.4*
20-29	2,237	*61.7*	109	*60.2*	111	*61.4*
≥30	608	*16.8*	21	*11.6*	24	*13.2*
Total	3,625	*100.0*	181	*100.0*	181	*100.0*

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TABLE II

CONTRACEPTIVE USE STATUS AT COMPLETION OF STUDY
DALKON SHIELD - PILL COMPARISON STUDY
MARYLAND COUNTIES - JULY 1970

Contraceptive Use Status	Shield Users		Pill Users	
	No.	%	No.	%
Accidental Pregnancy	4	2.2	14	7.7
Expulsion	7	3.8	-	- *
Discontinued, medical reason	15	8.3	13	7.2
Discontinued, personal reason	5	2.8	38	21.0
Discontinued, pregnancy desired	4	2.2	3	1.7
Release from Follow-up	5	2.8	20	11.0
Lost to Follow-up	14	7.7	15	8.3
Continuing Use	127	70.2	78	43.1
Total	181	100.0	181	100.0

*Category not applicable.

TABLE III

NET CONTINUATION RATES BY METHOD AND MONTHS OF USE
DALKON SHIELD - PILL COMPARISON STUDY
MARYLAND COUNTIES - JULY 1970

Months of Use	Shield Users		Pill Users	
	Rate	95% Confidence Limits	Rate	95% Confidence Limits
3	93.2	95.1 - 91.3	90.6	92.9 - 88.3
6	87.0	89.8 - 84.2	79.4	82.7 - 76.1
9	80.1	83.7 - 76.5	69.1	73.0 - 65.2
12	69.9	74.7 - 65.1	55.4	60.0 - 50.8

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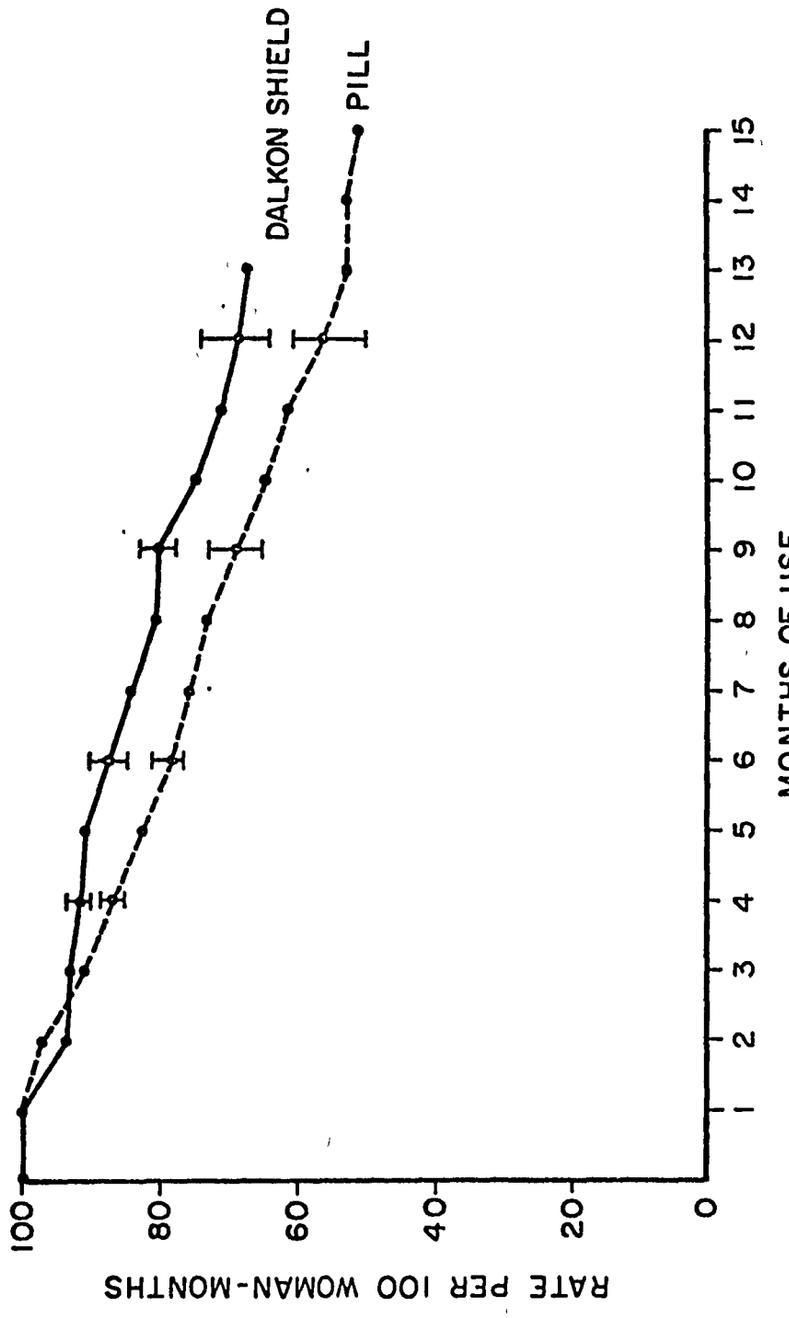

FIGURE 1. CONTRACEPTION CONTINUATION RATES, BY METHOD, SHIELD-PILL COMPARISON STUDY, MARYLAND STATE HEALTH DEPARTMENT, 1968-1970.

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Brooklyn, reported 1-year continuation rates of from 74.0 percent to 84.3 percent for IUD's and from 55.2 percent to 75.0 percent for orals (3). Recent follow-up studies in Taiwan found 1-year rates of 67 percent for the Lippes Loop and 31 percent for orals (4,5). Lippes reported rates of 80.1 percent for the Lippes Loop and 75.8 percent for orals in Buffalo clinics (6). Lippes suggested that some of the differences in rates between the two methods may be due to differences in age or other sociological variables in the two groups of users (6). The analyses of Hall and Tietze, who grouped patients by age, does not confirm this. They found that the differences in continuation rates occurred in most age groups (2,3).

The present study, in which age, race, and parity were controlled by careful matching procedures, also negates this hypothesis. Here it was found that a group of pill users of the same age, race, and parity as Dalkon Shield users still had lower continuation rates than the IUD users. Some other variable must be responsible for the difference.

One hypothesis is that patient motivation is involved in choice of method and thus affects the length of use of the method. Patients wanting a temporary method for purposes of child spacing may select orals; those wanting a more permanent method to limit family size may select an IUD. Some substantiation of this is found in the present study in the larger numbers of pill patients who were released from follow-up or who discontinued for personal reasons. This hypothesis could be adequately tested, however, only if it were possible to assign contraceptives to a group of volunteers by a random method, and this is not possible at present.

Another hypothesis is that the greater inconvenience of pills themselves is responsible for the lower continuation rate, that is, even if patients of equal levels of motivation were selected, pill users would still discontinue at a higher rate because of the extra effort involved in their use. This hypothesis would also be difficult to test at present

The absolute level of the continuation rates varies widely between the studies, from 63 percent to 84 percent for IUD's and from 31 percent to 76 percent for orals. In theory, the differences could be due to differences in which IUD was used, in the populations studied, in the clinic settings themselves, or in the methods of statistical analysis used. In practice, the absolute level of continuation rates is of less interest to a clinic administrator than is a difference in continuation rates between methods that he may wish to recommend to his clinics.

Reasons for termination, Table II, deserve some comment. The design of the study favored the pill in at least two ways. First, pill patients were given credit for some months use in which the pill may not actually have been taken. Second, of patients terminated as lost to follow-up, ones using the shield were more likely to be continuing to receive protection from pregnancy while those on pills were not. Given these biases in favor of the pill, the 14 terminations for accidental pregnancy among pill patients are quite striking when compared with only four pregnancies among

IUD users. Although the 14 pregnancies were probably due to improper use of the pill, and not to a defect in its theoretical effectiveness, they could be expected to occur in any large family planning program.

Numbers of patients discontinuing for medical reasons were almost equal in the two groups. Medical IUD removals were most often for pain, bleeding, or pain and bleeding. Pill patients discontinued for headaches, weight gain, or nausea. Numbers of patients discontinuing for planned pregnancies and numbers of patients lost to follow-up were also nearly equal.

More pill patients than IUD patients discontinued for personal reasons. These pill discontinuations were most often due to such reasons as "I am tired of taking them", "I can't remember to take them", or "They are a nuisance to take". Although most of these patients selected an alternate method, the statements reflect prevailing attitudes and a major disadvantage of the pill, namely, that it is a nuisance. In large clinics this characteristic, however trivial, cannot be ignored.

ACKNOWLEDGEMENTS

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